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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/515,513	02/29/2000	Wu Bo Li	0942.4870001/RWE	1139
26111	7590	05/09/2005	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			SISSON, BRADLEY L	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/515,513

Applicant(s)

LI ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 27-29 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 27-29 and 32-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 18 April 2005.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states:

All publications, patents and patent applications mentioned in this specification are indicative of the level of skill of those skilled in the art to which this invention pertains, and are herein incorporated by reference to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated by reference.

Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents.

2. Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In *re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

As set forth in *Ex parte Raible*, 8 USPQ2d 1707, (BPAI, 1998)

The examiner is of the opinion that the general incorporation by reference of the Bentley disclosure in appellant's specification is insufficient to support the specific disputed limitations of the present claims in the manner required by section 112 of the statute. We agree

* * *

We believe that the doctrine of incorporation by reference is of no avail to appellant in this regard since there is no specific indication in the instant specification of the particular features disclosed by Bentley which correspond to those intended for use in the here-claimed device; nor does the specification identify the specific portions of the patent which appellant may have intended to rely upon to supplement his disclosure. The purpose of incorporation by reference in an application of matter elsewhere written down is for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found. In re de Seversky , 474 F.2d 671, 177 USPQ 144 , (CCPA 1973).

Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Response to argument

3. At page 9, bridging to page 10 of the response applicant's representative asserts that an improper standard has been applied, that the present case is distinguishable over *Advanced Display Systems*, and that the objection should be withdrawn.
4. The above argument has been fully considered and has not been found to be persuasive. Assuming *arguendo* that the present application could be distinguished over *Advanced Display Systems*, the present case is on point with the decision in *Ex parte Raible*, and as such the standard applied is correct. Therefore, and in the absence of convincing evidence to the contrary, the objection is maintained.

Claim Objections

5. Claims 54-56 and 117 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

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required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 54-56 and 117 do not recite any lower limit to the temperature range. Such amendment effectively broadens the lower limit of the range recited in claim 47, from which they all depend. Applicant is urged to consider narrowing the range recited in said claims 54-56 and 117 such that the lower limit corresponds to a value encompassed by the range recited in parent claim 47.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 47, 49, 51-63, 107, and 111-117 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention”); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) (“the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed”). Thus, an applicant complies with the written-description requirement “by describing the

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invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

8. For convenience, claim 47, the sole independent claim pending, is reproduced below.

47. (currently amended) A method for synthesizing one or more cDNA molecules comprising ~~mixing~~ combining one or more mRNA templates, or one or more poly A RNA templates with at least one polypeptide having reverse transcriptase activity and an antibody or antibody fragment inhibitor of the polypeptide having reverse transcriptase activity, ~~under conditions that incubating said template, polypeptide and inhibitor at a temperature between 10°C and 90°C, inhibit, prevent or reduce the synthesis of non-specific cDNA products when compared to when said inhibitor is absent;~~ wherein said inhibitor inhibits said reverse transcriptase activity ~~under said conditions~~ at said temperature; and elevating said temperature to inactivate said inhibitor, whereby synthesizing one or more cDNA molecules are synthesized.

As seen above claim 47 has been amended so to recite that one is "incubating said template, polynucleotide and inhibitor at a temperature between 10°C and 90°C." At page 12, first full paragraph, of the response applicant's representative directs attention to page 5, lines 24-26, as providing support for this temperature range. For convenience, said passage is reproduced below.

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formation of mRNA secondary structures during cDNA synthesis. Preferably, temperatures for annealing or hybridizing primers to the templates range from about 10°C to about 90°C; more preferably about 10°C to about 80°C; still

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It is noted with particularity that the temperature range is to be used or “annealing or hybridizing primers to templates. Claim 47 does not recite the presence of any primer. (Claim 118 does introduce a primer into the mix.)

9. Claims 49, 51-63, 107, and 111-117, which depend from claim 47, fail to overcome this issue and are similarly rejected.

10. Should applicant desire to retain this temperature range in said claim 47, then applicant is urged to consider adding the limitation of claim into that of claim 47, otherwise, applicant is urged to consider using values of a temperature range that are more fully supported by the disclosure.

11. As set forth in claim 47, one is to employ” an antibody or antibody fragment inhibitor of the polypeptide having reverse transcriptase activity.” Claim 53 further stipulates that the “said inhibitor [said antibody or antibody fragment] inhibits, prevents, or reduces internal priming.” For purposes of examination, the “inhibitor” has been construed as being only the “antibody or antibody fragment,” and that said antibody or antibody fragment must possess all f the properties recited in both claims 47 and 53. A review of the specification finds support for where different antibodies or antibody fragments could be used that optionally have such properties (see page 13, first paragraph), however, the specification has not been found to support the newly added language such that antibodies or antibody fragments have all of these properties. Additionally, the specification has not been found to teach or suggest that applicant considered using antibodies that possess all of these properties.

12. For the above reasons and in the absence of convincing evidence to the contrary, the amendments to claim 47 constitutes new matter.

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13. While the specification refers to and claim 51 recites various reverse transcriptases, the specification has not been found to provide an adequate written description of just what the various structures are for the recited reverse transcriptases, much less which amino acids, and number of amino acids that may be substituted, deleted, and/or introduced into the various polypeptides such that they are encompassed by the reagents recited in said claim 51.

14. The amendment of 08 January 2001 added several new claims, including claims 57-59.

Page 13 of the response of 08 January 2001 states in part

I. Support for the Amendments

Support for the foregoing amendments to the claims may be found throughout the specification, and in the original claims. No new matter was added by way of this amendment.

15. A review of the disclosure fails to locate support for the ranges recited in said claims 57-59. Accordingly, and in the absence of convincing evidence to the contrary, said claims are rejected as containing new matter. Applicant is urged to indicate where support for these claims can be found or amend the claims such that the range recited is one supported by the disclosure, e.g., those found at page 5 where ranges in molar ratios are provided.

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 47, 49, 51-63, 107, and 111-118 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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18. As presently worded, claim 47 recites the temperature range of 10°C to 90°C, and also contains the statement that one is to “[elevate] said temperature to inactivate said inhibitor, whereby said one or more cDNA molecules are synthesized.” It is unclear if the “elevated” temperature falls within the recited range or above it.

19. Claims 51, 112, 113, and 114 have been found to contain abbreviations for which the full name is not given. Applicant is urged to consider amending the claims such that the full name followed with the abbreviation in parenthesis is used for the first instance in a series of dependent claims.

20. Claim 52 stipulates that “said reverse transcriptase is reduced in RNase H activity.” Said claim is indefinite with respect to what is the comparison being conducted and whether the reduction is statistically significant.

Conclusion

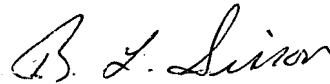
21. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
03 May 2005